09-15-04 IFW

Restriction Requirement – 35 USC 121

APPLICATION INFORMATION

Application Control Number: 10/801,520
Inventors: Mazzio and Soliman
Title: A topical treatment for dyshidrosis (pompholyx) and dry skin disorders
Art Unit: 1654
Patent Examiner: Michele Flood
Confirmation Number: 3209
Express Mail Number: ED 103156407 US

1. ELECTION OF INVENTION

The inventors respectfully elect the following invention without traverse as pursuant to 35 USC 121: We are requesting that the elected invention be restricted to "claims 1-16, drawn to a topical skin care composition comprising a safe and effective amount of claim-designated ingredients, classified in class 424, subclass 78.03 or 404 or 725". Invention I was elected pertaining to the product of claims 1-16, with cancellation of claims pertaining to the process of use (claims 17-21).

2. LIST OF ELECTED CLAIMS

What is claimed is:
1. A topical skin care composition comprising a safe and effective amount of:

a) one or more active ingredients selected from the group consisting of wormwood, black walnut and niacin;
b) aloe vera or a dermatologically acceptable carrier;
c) one or more active ingredients selected from the group consisting of garlic, turmeric, propolis, St. Johns wort, licorice, chamomile and herbal anti-bacterial agents.

2. A topical skin care composition according to claim 1, wherein said blackwalnut is further comprised of an extract derived from the species Juglans nigra or any plant from the genus Juglans, and constitutes about 9% and between 0.5%-90% by weight.

3. A topical skin care composition according to claim 1, wherein said wormwood is further comprised of an extract derived from the species Artemisia Absinthium or any plant from the genus Artemisia, and constitutes about 9% and between 0.5%-90% by weight.

4. A topical skin care composition according to claim 1, wherein said aloe vera or a dermatologically acceptable carrier constitutes about 54% and between 5-95 % by weight.

5. A topical skin care composition according to claim 1, wherein said turmeric is further comprised of an extract derived from the species Curcuma Longa or any plant from the genus Curcuma, and constitutes about 7% and between 0.5 % to 90 % by weight.

6. A topical skin care composition according to claim 1, wherein said licorice is further comprised of an extract derived from the species Glycyrrhiza Glabra or any plant from the genus Glycyrrhiza, and constitutes about 3% and between 0.5 to 25 % by weight.

7. A topical skin care composition according to claim 1, wherein said St. Johns wort is further comprised of an extract derived from the species Hypericum perforatum or any plant from the genus Hypericum, and constitutes about 3% and between 0.5 to 25 % by weight.

8. A topical skin care composition according to claim 1, wherein said chamomile is further comprised of an extract derived from the species Matricaria Chamomile or any plant from the genus Matricaria or Anthemis, and constitutes about 2% and between 0.5 to 25 % by weight.

9. A topical skin care composition according to claim 1, wherein said garlic is further comprised of an extract derived from the species Allium sativum or any plant from the genus Allium, and constitutes about 10% and between 0.75 to 70 % by weight.

10. A topical skin care composition according to claim 1, wherein said garlic further embodies a physical form of one or more selected from the group consisting of macerated, minced, diced, dried, pulverized, powdered, deodorized and shredded.

11. A topical skin care composition according to claim 1, wherein said propolis can be substituted for garlic and constitutes about 10% and between 0.75 to 70 % by weight.

12. A topical skin care composition according to claim 1, wherein said niacin is selected from the group consisting of niacinamide, nicotinic acid and chemical derivatives of niacin, constituting about 1% and between 0.02 to 5% by weight.

13. A topical skin care composition according to claim 1, wherein said herbal antibacterial agents are further comprised of extracts selected from the group consisting of clove, nutmeg, ginger, and myrrh, constituting about 2% and between 0.5 to 25% by weight.

14. A topical skin care composition according to claim 1, wherein said dermatologically acceptable carrier is further comprised of at least one selected from the group consisting of surfactants, binders, emulsifiers, bulking agents, starches, additives, diluents, stabilizers, preservatives, emollients, foaming agents, gels, sweeteners, thickeners, vehicles, coloring agents, fragrances, solvents, moisturizers, lubricants, deodorizers and buffers.

15. A topical skin care composition according to claim 1, wherein said dermatologically acceptable carrier is in the form of at least one selected from the group consisting of a suspension, solution, dispersion, lotion, liquid, gel, stick, capsule, foam, cream, pack, paste, coated glove or sock, salve, spray, aerosol, ointment, sponge, gel cap, granule, medicated bandage, medicated gauze, microparticles, nanospheres, microspheres, wipes, oil, powder and unique bio-delivery system.

16. A topical skin care composition according to claim 1, wherein said dermatologically acceptable carrier is further comprised of at least one selected from a group consisting of purified water, lanolin, lanolin alcohols, alcohols, vitamins, methylparaben, ethylparaben, butylparaben propylparaben, glycerin, vegetable oils, polysorbate, propylene glycol, para-aminobenzoic acid, mineral oil, carbomer, phospholipids, flour, starch, sorbitan laurate, carboxylic acids, triethanolamine, talc, titanium dioxide, antioxidants, gums, petrolatum, jojoba oil, isopropyl myristate, cetyl palmitate, sorbitan stearate, acids, base, cellulose, simethicone, butylated hydroxyanisole, butylated hydroxytoluene, glycol distearate, cetearyl alcohol, sorbitol, glyceryl stearate, cetearyl octanoate, dimethicone, wax, EDTA, sodium lauryl sulfate, glyceryl dilaurate, quarterium-15, calcium sulfate, calcium chloride, metal salts, gelatin, aloe vera and imidazolidinyl urea.

3. CANCELLATION OF CLAIMS TO THE NON-ELECTED INVENTION

17. A method of treating skin disorders in a mammal in need thereof, which comprises topically administering to said mammal an effective amount of the composition according to claim 1.

18. The method of claim 17, wherein said skin disorders are comprised of one or more symptoms selected from the group consisting of dry skin, skin lesions, cracks, fissures, scaling, discoloration, thickening, redness, bleeding, swelling, ulcers, sores, flaking, wounds, blistering, rashes, burns and loss of flesh.

19. The method of claim 17, wherein said skin disorders are comprised of one or more diseases selected from the group consisting of pompholyx, palmoplantar pustulosis keratolysis exfoliativa, atopic dermatitis, contact dermatitis, hand dermatitis, allergic dermatitis, gravitational dermatitis, asteatotic dermatitis, nummular dermatitis, seborrhoeic dermatitis, infective dermatitis, chronic superficial scaly acrodermatitis, chondrodermatitis, perioral dermatitis, dermatomyositis, neutrophilic dermatosis, dermatomyositis, transient acantholytic dermatosis, eczema, ichthyosis, xerosis, asteatosis, psoriasis, lupus erythematosus, urticaria and diseases of unknown origin.

20. The method of claim 17, wherein said skin disorders are further comprised of one or more diseases associated with initiating pathogens selected from the group consisting of yeasts, malassezia, candida, fungus, dermatophyte fungi, trichophyton, epidermophyton, microsporum, tinea, bacteria, staphylococcus, streptococcus, parasites, mites, scabies, lice, mold, scopulariopsis, aspergillus, fusarium, scytalidinium, viruses, coxsackie, enterovirus, herpes, parvovirus and epstein barr.

21. A therapeutic regimen for treating skin disease, wherein said niacin, in said topical skin care composition according to claim 1, can be administered through route of oral intake at a dose of 100-1000 mg/ day/ human.

Date: September 11, 2004

Signature Elizabeth Mazzio

Elizabeth Mazzio

Office Action Summary	Application No.	Applicant(s)	
	10/801,520	MAZZIO ET AL.	
	Examiner	Art Unit	
	Michele Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 16, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-21* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-16, drawn to a topical skin care composition comprising a safe and effective amount claim-designated ingredients, classified in class 424, subclass 78.03 or 404 or 725, for example.

II. Claims 17-21, drawn to a method of treating skin disorders in a mammal in need thereof which comprises topically administering to the mammal an effective amount of the composition according to claim 1, classified in class 514, subclass 861 or 863 or 864, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product, as evidenced by the teachings of Takekoshi, in U.S. 6,517,846.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for another Group, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: the distinct disease-conditions of Claims 17-20.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 14-16 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PATENT EXAMINER

MCF
August 6, 2004

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,520	03/16/2004	Elizabeth A. Mazzio		3209

7590 08/13/2004

Elizabeth A. Mazzio
982 West Brevard Street, D #22
Tallahassee, FL 32304

EXAMINER	
FLOOL, MICHELE C	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.